

**TIME SENSITIVE PATENT INFORMATION PURSUANT TO
21 C.F.R. 314.53 (c) FOR NDA # 20-553**

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

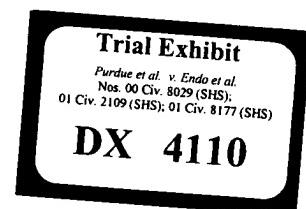
Trade Name: OxyContin®
Active Ingredient(s): Oxycodone Hydrochloride
Strength(s): 10, 20, 40, 80 and 160 mg
Dosage Form: Extended-Release Tablets
Approval Date: 10 mg. - December 12, 1995
20 mg. - December 12, 1995
40 mg. - December 12, 1995
80 mg. - January 6, 1997
160 mg. - March 15, 2000

Applicant: Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

Listed Drug: OxyContin® (Oxycodone Hydrochloride) Controlled-Release Tablets
Indication(s): OxyContin® (Oxycodone Hydrochloride) Controlled-Release Tablets are indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

**Confidential Information
Purdue v. Endo**

P 650650



1. United States Patent No. 4,861,598

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 4,861,598Expiration Date: August 29, 2006Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)

 Y X N

Drug Product (Composition/Formulation)

 X Y N

Method of Use

 Y X N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A

Name of Patent Owner: Euro-Celtique S.A.U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 4,861,598 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650651

2. United States Patent No. 4,970,075

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 4,970,075

Expiration Date: August 29, 2006

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)

 Y X N

Drug Product (Composition/Formulation)

 X Y N

Method of Use

 Y X N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A.

Name of Patent Owner: Euro-Celtique S.A.

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 4,970,075 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

X currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650652

3. United States Patent No. 5,266,331

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,266,331

Expiration Date: October 26, 2007

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)

Y N

Drug Product (Composition/Formulation)

Y N

Method of Use

Y N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:

N/A

Name of Patent Owner:

Purdue Pharma L.P.
The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,266,331 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650653

4. United States Patent No. 5,508,042

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,508,042

Expiration Date: April 16, 2013

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)

Y X N

Drug Product (Composition/Formulation)

Y X N

Method of Use

X Y N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner:

Purdue Pharma L.P.

The Purdue Frederick Company

The P.F. Laboratories, Inc.

The Purdue Pharma Company

U.S. Agent (*If patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,508,042 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650654

5. United States Patent No. 5,549,912

A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,549,912

Expiration Date: October 26, 2007

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)

 Y X N

Drug Product (Composition/Formulation)

 X Y N

Method of Use

 Y X N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
N/A.

Name of Patent Owner:

Purdue Pharma L.P.
 The Purdue Frederick Company
 The P.F. Laboratories, Inc.
 The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,549,912 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

X currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

 the subject of this application for which approval is being sought.

Confidential Information
Purdue v. Endo

P 650655

6. United States Patent No. 5,656,295

- A. This information should be provided for each individual patent submitted:

U.S. Patent Number: 5,656,295

Expiration Date: October 26, 2007

Type of Patent (*indicate all that apply*):

Drug Substance (Active Ingredient)

Y N

Drug Product (Composition/Formulation)

Y N

Method of Use

Y N

- a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:
Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner:

Purdue Pharma L.P.
 The Purdue Frederick Company
 The P.F. Laboratories, Inc.
 The Purdue Pharma Company

U.S. Agent (*if patent owner or applicant does not reside or have place of business in the U.S.*):
Philip C. Strassburger, Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

- B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,656,295 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

the subject of this application for which approval is being sought.

Signed:


 Philip C. Strassburger
 U.S. Patent and Trademark Office Registration No. 34,258

Date: March 28, 2002

Confidential Information
Purdue v. Endo

Title: Vice President, Intellectual Property Counsel
 Purdue Pharma L.P.

Telephone Number: (203) 588-7639

P 650656